

Implex Corp.
Ceramic Head 510(K)
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**510(k) Summary of
Safety and Effectiveness**

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Product: **Classification Name:** Ceramic Femoral Head Component of Hip Joint,
Metal/Ceramic/Polymer, Semi-constrained Cemented or Non-Porous
Uncemented Prosthesis (21 CFR 888.3353)

Generic Name: Ceramic Femoral Head Component of a Total Hip
Replacement

Trade/Proprietary Name: Implex Ceramic Head

Substantially Equivalent Products:

PROZYR™ Zirconium Oxide Ceramic Head from Smith & Nephew Richards, Inc.
Ceramic Bearing Head from Osteonics, Corp.
Modular Ceramic Heads from Biomet, Inc. (K925345)
Zr Ceramic Heads from Howmedica (K952418 & K946026)

Description: The Implex Ceramic Head is a ceramic femoral head. It is a spherical ball made from zirconia ceramic which has a tapered bore on one end of it. It is provided in one external diameter (28mm) and two (2) neck lengths (+0 Short, +6 Standard).

Intended Use: The Implex Ceramic Head is intended to provide articulation in cases of:

1. Severely disabled joints as a result of degenerative arthritis or avascular necrosis.
2. Secondary revision of a previously unsuccessful femoral component or total hip replacement.
3. Other hip problems where clinical experience has shown that alternative modes of treatment are less likely to achieve satisfactory results.
4. Fracture dislocation of the hip or irreducible fractures in which adequate fixation cannot be obtained.
5. Non-union of femoral neck or head fractures.
6. Salvage of a failed primary or secondary total or hemi hip.

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The Implex Ceramic Head is intended to be used in either cemented or uncemented applications depending on the intended use of the femoral stem it is mated with.

Comparison to Substantially Equivalent Products:

All of the named ceramic heads use Zirconia ceramic materials. These materials have a history of demonstrated success as implant materials for femoral heads.

The Implex Ceramic Head is available in an outer diameter of 28mm and neck lengths of +0mm and +6mm. The other heads have outer diameters of 26mm, 28mm and 32mm and neck lengths of -5mm, -3mm, 0mm, +3mm, +4mm, +5mm, +6mm and +8mm.

All of the named ceramic heads are used to reconstruct the hip joint in combination with femoral stem and acetabular cup to provide appropriate joint spacing and femoral/acetabular articulation. In addition, all of the products are intended to be used in cemented or cementless applications.

All of the named ceramic heads are spherical, with a tapered bore manufactured in one end.